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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,143	03/05/2002	Todd Allen Berg	293/034 CONT2	7997

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EXAMINER

WOO, JULIAN W

ART UNIT PAPER NUMBER

3731

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,143

Applicant(s)

BERG ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 49-51 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-11, 14, 15, 18, 20, 21, 23, 24, 28-48 and 52-57 is/are rejected.
- 7) ☒ Claim(s) 12, 13, 16, 17, 19, 22 and 25-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4, 7, 11/02, 10/03, 7/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. The Examiner hereby acknowledges the election of claims 5-48 and 52-57, without traverse in the response of July 28, 2004.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 45 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 45, it is uncertain as to what angle the cylinder-like portion is disposed, since "perpendicular" generally means 90 degrees. With respect to claim 46, "said certain angle" lacks antecedent basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 5-8, 11, 18, 20, 21, 23, 28-39, 47, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Marin et al. (5,397,355). Marin et al. disclose, in

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the figures and in col. 1, lines 47-68, an anastomotic connector having a radially-expandable cylinder-like portion with a lumen of a circular cross-section, two ends, and cells-elements (12), and tissue engaging portions (19) comprising at least one and at least a second set of extendable spikes adjacent the two ends, where the spikes are arranged to bend at at least two points (20, 22), where the spikes (along the longitudinal axis) are arranged to bend towards one another and are arranged in a same plane (circumferential) when in a bent configuration, where the lumen is matched to a coronary artery, where the cell elements have a parallelogram geometry (see fig. 1) or an outline geometrical shape and are arranged in axial and circumferential bands, where the cell elements are arranged to distort out of a plane of the cells (to a plane with a larger radius of curvature), where the cell elements are not planar, where the cell elements meet at junctions connected by substantially rigid struts (at 14, axially) and flexible wires (at 16, circumferentially), where the tissue engagers are adapted to engage everted and non-everted grafts. Note: The introductory statement of intended use ("for attaching two blood vessels") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Marin et al., which is capable of being used as claimed if one desires to do so.

6. Claims 7, 9, 10, 14, 24, 42-46, 52-55, and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Kleshinski (5,755,778). Kleshinski discloses, in figures 5-7 and in col. 6, lines 7-34, an anastomotic connector (50) with a cylinder-like portion or collar section with cell elements defining a lumen of a polygonal cross-section and a plurality of tissue-engaging portions (74) or spike section comprising spikes,

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where the spikes lie in a plane perpendicular to the cylinder-like portion, where the spikes are arranged to bend at angle or at least 90 deg. (see fig. 6), where the connector is adapted for side-to-end anastomosis and sealing by radial pressure by the cylinder-like portion, where the spike section comprises a super-elastic material (nitinol), where the spikes have a hook shape, and where the collar section is adapted to form an oblique anastomosis.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marin et al. Marin et al. disclose the invention substantially as claimed, but do not disclose that the spike is arranged to bend at least 150 deg. when it extends. Nevertheless, it would have been a matter of design choice to bend the spike at the claimed angle. The choice

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would be dependent upon the size of the vessel, where the device is connected and the degree of expansion of the cylinder-like portion within the vessel.

9. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marin et al. in view of Lau et al. (5,735,893). Marin et al. disclose the invention substantially as claimed, but do not disclose that portions of the device comprise a temperature-triggered shape memory material. Lau et al. teach, in col. 2, lines 39-59, a stent comprising a temperature-triggered shape-memory material (NiTi alloys). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Lau et al., to manufacture the device of Marin et al. out of a temperature-triggered shape-memory material. Such a material is not only biocompatible, it possesses the strength and flexibility for expansion of the device within a vessel and for structural support of the vessel lumen.

10. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kleshinski. Kleshinski discloses the invention substantially as claimed, but does not disclose a collar section adapted to from a perpendicular anastomosis. Nevertheless, it would have been a matter of design choice to adapt the collar section for such an anastomosis. The choice for an angle of the collar section would be dependent upon the orientation of the vessels being connected, where the orientation could demand a perpendicular anastomosis.

Allowable Subject Matter

11. Claims 12, 13, 16, 17, 19, 22, and 25-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an connector having, inter alia, a cylinder-like portion with lumen and spikes, where each spike comprises a protrusion, where each spike is arranged to bend at least 180 deg. or 210 deg. or in a continuous curve when it extends, where the lumen has an elliptical cross-section, and where the lument has a varying inner diameter.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo
Primary Examiner

December 27, 2004